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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,846	10/31/2003	Farid Bruce Khalili	622/20	8064
27538 7590 01/05/2010 GIBSON & DERNIER LLP 900 ROUTE 9 NORTH SUITE 504 WOODBIDGE, NJ 07095				
EXAMINER PELLEGRINO, BRIAN E				
ART UNIT 3738		PAPER NUMBER		
MAIL DATE 01/05/2010		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/696,846

Applicant(s)

KHALILI, FARID BRUCE

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 8-10, 17, 18 and 20-26 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 8-10, 17, 18 and 20-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/09 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(b) because they are incomplete. 37 CFR 1.83(b) reads as follows:

When the invention consists of an improvement on an old machine the drawing must when possible exhibit, in one or more views, the improved portion itself, disconnected from the old structure, and also in another view, so much only of the old structure as will suffice to show the connection of the invention therewith.

For example the new feature being claimed of a middle component that includes at least one raised wing surface that tapers downwardly toward at least one outside edge of the middle component must be shown in complete view with the base component that is claimed (claim 17) to have a concave portion to accommodate a convex portion of the middle component. It appears the claim (25) is directed to Fig. 6 showing a tapered middle component. The interior portion of the base component claimed as being concave (claim 17) does not appear to accommodate such a feature. Additionally, the

base component having a rim disposed on or around the concave portion of its surface must be shown to illustrate the complete version of the assembled claimed invention. A clip and base component to receive the clip is not shown to illustrate what and how this envisaged. The drawings are required to show every feature of the claimed invention. In this instance no complete assembled version is illustrated to show these claimed features.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2,3,8,9,17,18,20,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazda (WO 94/04100) in view of Alfaro et al. (2001/32017) and Michelson (6120503). Mazda shows (Fig. 5) a spinal implant with a first base component **25**, a second base component **26**, and a middle component **22** having a convex side **9**. The first base component having a second side that comprises a concave portion **12** with a constant radius to engage the convex surface of the middle component. As seen in Fig. 5, there are a plurality of sharpened teeth **17** and are positioned on each side of the top and bottom components for **engaging** vertebrae. However, Mazda fails to disclose the surface for engaging vertebrae includes a pair of concentric raised circular portions stacked on one another with angled sidewalls that taper inwardly in the direction towards the base component. Alfaro et al. teach (Figs. 1,11) that the vertebral engaging surface of the implant includes a pair of circular raised portions stacked on top of one another for the top and bottom surfaces of the spinal implant. Michelson teaches (Figs. 9,11) stacked bone engagement portions with angled sidewalls that taper in the direction towards the surface of the base component. Michelson additionally shows (Fig. 13E) that the cross-section of the bone penetrating portions that are stacked can be tapered inwardly. Michelson further teaches that the stacked and angled inward tapering provides a force as being inserted into vertebrae, col. 8, lines 45-54,63,64. It would have been obvious to one of ordinary skill in the art to

incorporate the circular stacked raised portions as taught by Alfaro et al. with the spinal implant of Mazda since it would complement the spinal space more naturally, see Alfaro (paragraph 11). Further it would have been obvious to additionally modify the stacked raised portions to be tapered inwardly as taught by Michelson with the spinal implant of Mazda as modified by Alfaro et al. such that it firmly engages the vertebrae and assures it is properly seated within the vertebral bones. Regarding claim 8, it can be seen the middle component is removably or slidably received in slot 28 such that the convex portion extends above the "generally" flat portion of the inner second side of the second base component. It can be construed that grooves in the plates for the screw in teeth lie below the flat surface and surround the convex component. With respect to claim 9, it can be seen in Fig. 2 of Mazda that the center of the middle component is closer to one edge than the other. Regarding claim 18, Fig. 6 of Mazda show the teeth are positioned near the periphery and Alfaro teaches the stacked circular raised portions are centrally located. With respect to claim 20, it can be seen (Fig. 3) that the incorporated raised portions taught by Alfaro et al. are shown with flat top surfaces. Regarding claim 21, it can be seen (Fig. 5) of Mazda that the inner surface of the base component is raised and slidably receives the middle component.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazda (WO 94/04100) in view of Alfaro et al. (2001/32017) and Michelson '503 as applied to claim 17 above, and further in view of Khandkar et al. (2004/133281). Mazda is explained above. However, Mazda fails to disclose the middle component varies in height from posterior to anterior edges. Khandkar et al. teach (Fig. 8) that middle

component **42** varies in height from posterior to anterior edges to provide limited amount of axial rotation and translation, Paragraph 73. It would have been obvious to one of ordinary skill in the art to modify the middle component to be varied in height as taught by Khandkar et al. in the spinal implant of Mazda modified with Alfaro et al. and Michelson such that it limits movement in a patient that can only have limited motion.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazda (WO 94/04100) in view of Alfaro et al. (2001/32017) and Michelson '503 as applied to claim 21 above, and further in view of Errico et al. (6989032).

Mazda as modified with Alfaro and Michelson is discussed above. However, Mazda in view of Alfaro and Michelson fail to disclose the raised portion has apertures and the middle component is secured via a clipping element. Errico et al. show (Figs. 1i,1j) base component with raised portion **40** and apertures **44** to secure a middle component **31** using clipping elements **46**. It would have been obvious to one of ordinary skill in the art to incorporate a plurality of apertures in the raised portion of the plate and use clipping elements as taught by Errico et al. with spinal implant of Mazda as modified with Alfaro and Michelson such that the components cannot become dislodged or misaligned. Regarding claim 24, it can also be seen (Fig. 1i) that Errico teaches the middle component **31** contains a slot **33** for flexibility. It would have also been obvious to one of ordinary skill in the art to incorporate a slot in the middle component as taught by Errico et al. with the device of Mazda as modified by Alfaro and Michelson such that it can impart some compressibility. It is understood that since the

middle component is disposed within the raised portion wall of the device of Mazda, it can be said that a slot would engage the raised portion at some point.

Claims 25,26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazda (WO 94/04100) in view of Alfaro et al. (2001/32017) and Michelson '503 as applied to claim 17 above, and further in view of Buettner-Janz et al. (4759766).

Mazda as modified with Alfaro and Michelson is discussed above. However, Mazda in view of Alfaro and Michelson fail to disclose the middle component have a circumferential groove and a rim disposed around the concave portion of the base component or a wing that tapers. Buettner-Janz show (Fig. 2) a middle component **4** of a spinal implant with a circumferential groove **5** that is formed between the middle component and a wing **6** that tapers down to the middle component for matching with rim **2** of base components shown in Figs. 1,3. Buettner-Janz teach the groove provides a guide for preventing over rotation and possible slip out of middle component, Col. 5, lines 6-11. It would have been obvious to one of ordinary skill in the art to incorporate a circumferential groove and the wing about the middle component of Mazda's spinal implant as modified with Alfarao and Michelson per the teaching of Buettner-Janz such that over rotation is prevented and any risk of slip out.

Response to Arguments

Applicant's arguments with respect to claim 17 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bagby (5885287) show that top and bottom surfaces include inward tapered projections on top and bottom surfaces of a spinal implant. Williams (6113638) teach a tapered middle component for placement between two base components.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738